510(k) Summary

SEP 1 9 2001

K012371

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, IN 46250
(317) 576 - 3544

Contact Person: Sherri L. Coenen

Date Prepared: July 26, 2001

Device Name

Proprietary name: Tina-quant Transferrin ver.2

Common name: Transferrin

Classification name: Transferrin immunological test system

Device Description

The Tina-quant Transferrin ver.2 Assay is based on the principle of immunological agglutination. Anti-transferrin antibodies react with the antigen in the sample to form an antigen/antibody complex. Following agglutination, this is measured turbidimetrically. Addition of PEG allows the reaction to progress rapidly to the end point and increases sensitivity.

Substantial equivalence - similarities

The following table compares the Tina-quant Transferrin ver.2 Assay with the predicate device.

Feature	Tina-quant Transferrin ver.2	Tina-quant Transferrin
Intended Use	Immunoturbidometric assay for the in vitro quantitative determination of transferrin in human serum and plasma on automated clinical chemistry analyzers.	Immunoturbidometric assay for the in vitro quantitative determination of transferrin in human serum and plasma on automated clinical chemistry analyzers.
Indication for Use	A transferrin immunological test system is a device that consists of the reagents used to measure by immunological techniques the transferrin (an iron-binding and transporting serum protein) in serum and plasma. Measurement of transferrin levels aids in the diagnosis of malnutrition,acute inflammation, infection, and red blood cell disorders,such as iron deficiency anemia.	A transferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the transferrin (an iron-binding and transporting serum protein) in serum, plasma, and other body fluids. Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders, such as iron deficiency anemia.
Assay Protocol	Immunoturbidimetric	Immunoturbidimetric
Instrument	Roche/Hitachi Clinical Chemistry Analyzers	Roche/Hitachi Clinical Chemistry Analyzers
Sample Type	Human serum and plasma	Human serum and plasma
Traceability / Standardization	Standardized against the reference preparation CRM 470, corresponding to RPPHS (Reference Preparation Protein in Human Serum)	Standardized against the reference preparation CRM 470, corresponding to RPPHS (Reference Preparation Protein in Human Serum)

Substantial equivalence - differences

The following table compares the Tina-quant Transferrin ver.2 assay with the predicate device.

Feature	Tina-quant Transferrin ver.2	Tina-quant Transferrin
Antibody source	rabbit	goat
Measuring Range	Roche/Hitachi 704/902 0.02 – 5.00 g/l (1 – 500 mg/dl) Maximum reportable range is dependent on the highest standard concentration.	Roche/Hitachi 704/902 80 – 500 mg/dl Maximum reportable range is dependent on the highest standard concentration.
	Roche/Hitachi 717/747 0.02 – 5.00 g/l (1 – 500 mg/dl) Extended measuring range with rerun 0.02 – 7.50 g/l (1 – 750 mg/dl) Maximum reportable range is dependent on the highest standard concentration.	Roche/Hitachi 717/747/914 80 – 500 mg/dl Extended measuring range with rerun 80 – 1000 mg/dl Maximum reportable range is dependent on the highest standard concentration.
	Roche/Hitachi 904/911/912/917/ Modular P 0.007 – 5.20 g/l (0.7 – 520 mg/dl) Extended measuring range with rerun 0.007 – 7.80 g/l (0.7 – 780 mg/dl) Maximum reportable range is dependent on the highest standard concentration.	Roche/Hitachi 904/911/912/917/ Modular P 15 – 500 mg/dl Maximum reportable range is dependent on the highest standard concentration.

Substantial equivalence – performance characteristics

The performance characteristics of the Tina-quant Transferrin ver.2 Assay and the predicate device are compared in the table below.

Feature	Tina-quant Transferrin ver.2	Tina-quant Transferrin
Intra-assay precision (% CV)	Human sera: 1.0% at 1.36 g/l (136 mg/dl) 2.7% at 3.59 g/l (359 mg/dl)	Human sera: 0.8% at 169 mg/dl
	Controls: 2.1% at 2.90 g/l (290 mg/dl) 1.0% at 4.31 g/l (431 mg/dl)	Controls: 0.8% at 217 mg/dl 0.8% at 403 mg/dl
Between Day Precision (% CV)	Human sera: 0.0% at 1.60 g/l (160 mg/dl) 1.4% at 3.38 g/l (338 mg/dl)	Human sera: 3.0% at 169 mg/dl
	Controls: 1.7% at 2.88 g/l (288 mg/dl) 1.4% at 4.35 g/l (435 mg/dl)	Controls: 1.4% at 217 mg/dl 1.5% at 403 mg/dl

Substantial equivalence – performance characteristics, cont.

The performance characteristics of the Tina-quant Transferrin ver.2 Assay and the predicate device are compared in the table below.

Feature	Tina-quant Transferrin ver.2	Tina-quant Transferrin
Limitations	• Icterus: No significant interference with up to an I index of 60 • Hemolysis: No significant interference up to an H index of 1000 • Lipemia (Intralipid): No significant interference up to an L index of 500 • Rheumatoid factors < 1200 IU/ml do not interfere • Gammopathy type IgM sera (Waldenstroem's macroglobulinemia) interfere with the assay	• Icterus: No significant interference from bilirubin up to an I index of 60 • Hemolysis: No significant interference from hemoglobin up to an H index of 1000 • Lipemia (Intralipid): No significant interference from lipemia up to an L index of 600 • Rheumatoid factors < 350 IU/ml do not interfere
Analytical sensitivity (LDL)	Roche/Hitachi 704/717/747/902 0.02 g/l (1 mg/dl) Roche/Hitachi 904/911/912/917/Modular P 0.007 g/l (0.7 mg/dl)	15 mg/dl
Method comparison	Tina-quant Transferrin ver.2 (Y) / Tina-quant Transferrin (X): Passing/Bablock: y = 0.01 + 0.97x r = 0.990	Tina-quant Transferrin on Roche/Hitachi 917 (Y)/ Tina-quant Transferrin on Roche/Hitachi 911 (X): Passing/Bablock: y = 1.141 + 0.989x r = 0.998

Substantial equivalence – performance characteristics, cont.

The performance characteristics of the Tina-quant Transferrin ver.2 Assay and the predicate device are compared in the table below.

Feature	Tina-quant Transferrin ver.2	Tina-quant Transferrin
Calibration frequency	• after reagent lot change • as required following quality control procedures	• after reagent lot change • as required following quality control procedures
Expected values	2.0 – 3.6 g/l (200 – 360 mg/dl)	IFCC/CRM 470: 200 – 360 mg/dl Roche: 200 – 400 mg/dl

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
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SEP 1 9 2001

Ms. Sherri L. Coenen
Regulatory Submissions, Centralized Diagnostics
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K012371
Trade Name: Roche Diagnostics Tina-quant® Transferrin ver.2
Regulatory Class: 21 CFR § 866.5880
Regulatory Class: II
Product Code: DDG
Dated: July 26, 2001
Received: July 26, 2001

Dear Ms. Coenen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Roche Diagnostics Corp

510(k) Number (if known): K012371

Device Name: Tina-quant Transferrin ver.2

Indications For Use:

Immunoturbidometric assay for the in vitro quantitative determination of transferrin in human serum and plasma on automated clinical chemistry analyzers. A transferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the transferrin (an iron-binding and transporting serum protein) in serum and plasma. Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders, such as iron deficiency anemia.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan S. Alpaugh

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K012371